STATUS OF CLAIMS

Claims 1-4, 6-14 and 16-38 are pending in the application. Claims 5 and 15 were previously cancelled and claims 22-32 were previously withdrawn from consideration pursuant to a restriction requirement. Thus, claims 1-4, 6-14, 16-21 and 33-38 are presented for examination.

In Applicant's prior response dated March 30, 2010, claims 1 and 37 were amended. Support for the amendment to claims 1 and 37 is provided in the original claims as filed, particularly original claim 15. See also paragraphs [0014], [048] and [0058] of the specification. No new matter was added.

REMARKS

Clarification

As a preliminary matter, in a telephone conversation with Examiner Betton on September 1, 2010, the Examiner confirmed to the undersigned that the only outstanding rejections in the present application are the rejections to follow under 35 USC 103 (i.e., there are no outstanding rejections under other statutory provisions, including 35 USC 112).

Rejection Under 35 U.S.C. § 103(a) Seo and Desai in view of Gentz, Cortese, and Glajch

Claims 1-4, 6-14, 16-21 and 33-38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Seo et al. (U.S. Pat. 6,277,391) and Desai et al. (U.S. Appln. Pub. No. 2003/0130575) in view of Gentz et al. (U.S. Pat. No. 6,869,927), Cortese et al. (U.S. Appln. Pub. No. 2002/0010150) and Glajch et al. (U.S. Pat. No. 5,147,631). This rejection is respectfully traversed.

The combined references do not teach or suggest all of the claimed features of the claimed invention, as argued below. In addition, Applicant has amended independent claim 1 as follows, rendering the rejection moot:

> An injectable or insertable dosage form for producing specific necrosis of tissue that comes into contact with the dosage form comprising: a biodisintegrable binder and a chemical ablation agent in a concentration

> effective to cause necrosis of said tissue, wherein said dosage form is a sterile, solid or semi-solid dosage form***, and said biodisintegrable binder comprises first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form.***

The cited references, either singly or in combination, do not teach or suggest all of the features of the claimed invention. Among other things, the cited prior art fails to teach the feature of claim 1 that is highlighted above.

Seo et al. teaches "a method of treating diseases and disorders of the prostate by injecting biodegradable microspheres containing a treatment substance directly into the prostate." (Seo et al., col. 4, lines 42-45). It does not teach a chemical ablation agent. Further, it does not teach first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form. In fact, the words "crosslink," "crosslinking," "crosslinked" or "crosslinkable" are found nowhere in Seo et al.

Desai et al. teaches "a method of tissue treatment including injection of radiation activating/enhancing agents and photoselective/photosensitive agents and viscous substances to cause controlled necrosis of target tissue from selective absorption of laser energy and/or electromagnetic radiation to cause controlled and selective tissue necrosis." (Desai et al., paragraph [0010], col. 1, lines 24-29). It does not teach a chemical ablation agent. Further, it does not teach first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form. In fact, the words "crosslink," "crosslinking, "crosslinked" or "crosslinkable" are found nowhere in Desai et al.

The secondary references do not remedy these deficiencies. The Examiner cites Gentz et al. for purportedly teaching "sodium chloride as a tonicifier at a concentration of from about 0 to about 150 mM (NACl) [sic]." Even if it were assumed that Gentz et al. teaches what the Examiner purports that it does, Gentz et al. still fails to address the features of the claimed invention that are missing from the primary references Seo et al. and Desai et al. For

example, even if it were assumed that the sodium chloride tonicifier of Gentz et al. reads upon the claimed "chemical ablation agent," nowhere does Gentz et al. teach first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form. Further, even if we were to assume for the sake of argument that the Examiner's assertion that Gentz et al. teaches "ionically cross-linkable polymers such as alginate polymer" is correct, Gentz et al. still fails to remedy the deficiencies of the primary references because it fails to teach ***a biodisintegrable binder that comprises first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form.***

Cortese et al. teaches "compositions and methods of promoting hemostatis…and/or wound healing." (Cortese et al., paragraph [0067]). The passages that the Examiner points to disclose a "possible mechanism for formation of cross-linked gels and foams for this invention discussed in U.S. Pat. No. 8,906,997" (Cortese et al. paragraph [0069]) and disclose that "to make PA/PO [polyacid/polyalkylene oxide] foams, typically a mixture of PA/PO gel is exposed to increased pressure in the presence of a charging gas." (Cortese et al., paragraph [0106]). Nowhere does Cortese et al. teach a chemical ablation agent. Nowhere does Cortese et al. teach first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form. In fact, the words "crosslink," "crosslinking, "crosslinked" or "crosslinkable" are found nowhere in Cortese et al.

Glajch et al. is cited by the Examiner for purportedly teaching "the general knowledge in the art regarding formulations comprising contrast agents, polymers, and solid particles." Even assuming for the sake of argument that Glajch et al. teaches what the Examiner purports it does, Glajch et al. fails to remedy the deficiencies of the primary references. Nowhere does Glajch et al. teach a chemical ablation agent. Nowhere does Glajch teach first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form. In fact, the words

"crosslink," "crosslinking, "crosslinked" or "crosslinkable" are found nowhere in Glajch et al. Even if, for the sake of argument, it were assumed that all five references teach what the Examiner asserts, the combination of still fails to establish a *prima facie* case of obviousness. MPEP 2143 provides a number of various rationales that may be utilized by the Examiner to meet the basic requirements of a *prima facie* case of obviousness.

However, a *prima facie* case of obviousness cannot be established by this combination of references because of a very basic and critical deficiency. Here, the combination does not teach or suggest ***all of the claim elements***, as required. Namely, the combination fails to remedy the deficiency of Seo et al. and Desai et al., which fail to teach ***a biodisintegrable binder that comprises first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form.*** "When determining whether a claim is obvious, an examiner must make 'a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.' … Thus, 'obviousness requires a suggestion of all limitations in a claim.' …" *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733, January 14, 2008, *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original).

There is no substitution offered for the missing claim features or a ***finite number of identified, predictable solutions*** that would have made such purported substitutions "obvious to try." *Takeda Chemical Industries, Ltd. V. Alphapharm Pty., Ltd.,* 492 F.3d 1350 (Fed. Cir. 2007)(emphasis added). There is simply no teaching or suggestion of a biodisintegrable binder that comprises first and second biodisintegrable polymers with at least one being crosslinked at an outer surface of the dosage form.

Given the above remarks, Applicant states that a *prima facie* case of obviousness has not been established and states that the Examiner's rejection under 35 U.S.C § 103(a) has been obviated and respectfully requests that the Examiner withdraw the rejections. Claim 1 is an independent claim, and the above comments apply directly to it. All other rejected claims

are dependent directly on claim 1 and the rejection of those claims fails at least because of the fundamental defect discussed above.

Rejection Under 35 U.S.C. § 103(a) Seo and Gentz in view of Desai, Cortese, and Glajch and further in view of Hauschild, Escandon, Unger, Unger, and Unger

Claims 2-4 and 33-38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Seo et al. (U.S. Pat. No. 6,277,391), Gentz et al. (U.S. Pat. No. 6,869,927) in view of Desai et al. (U.S. Appln. Pub. No. 2003/0130575), Cortese et al. (U.S. Appln. Pub. No. 2002/0010150) and Glajch et al. (U.S. Pat. No. 5,147,631) as applied to claims 1 and 6-21 above, and further in view of Hauschild et al. (U.S. Patent No. 6,905,475), Escandon et al. (U.S. Patent No. 7,015,253), and Unger et al. (U.S. Patent Nos. 5,733,572 (Unger '572), 6,443,898 (Unger '898), and 6,123,923 (Unger '923)).

In response, Applicants respectfully traverse the rejection and its accompanying remarks. Applicant reiterates the arguments made regarding the references Seo et al. and Gentz et al. above. In addition, Applicant presents the following arguments.

In a previous rejection which has since been withdrawn, the Examiner had rejected the claims as unpatentable for obviousness in light of Hauschild et al., Escandon et al. and the Unger references. The Examiner now rejects claims 2-4 and 33-38 over Seo et al. and Gentz et al. and cites Hauschild et al., Escandon et al., and the Unger references as secondary references.

Applicant respectfully states that despite the addition of Seo et al. and Gentz et al., the combination of references still fails to teach or suggest every feature of the claimed invention. Despite the large number of primary and secondary references that the Examiner has combined (eleven references in total), the combination still does not teach the invention of the claims. Notably missing is any teaching or suggestion of the following feature contained in independent claims 1 and 37 (upon which the rejected claims depend): ***biodisintegrable binder comprising first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer***

surface of the dosage form. In fact, Applicant respectfully points out that the fact that the Examiner has cobbled together so many references (11) to make his obviousness argument underscores the lack of teaching or suggestion in the art.

Although the fact that the Examiner has combined a large number of references to mount his obviousness rejection does not, in and of itself, vitiate a *prima facie* case of obviousness, Applicant submits that it is the Examiner's burden to make "a searching comparison of the claimed invention - *including all its limitations* - with the teaching of the prior art." *See In re Wada and Murphy*, Appeal 2007-3733, *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original). Applicants respectfully submit that the Examiner has failed to make such "searching comparison" of all of the claim limitations with respect to the cited prior art. For example, Applicant states that the Examiner did not make a searching comparison to establish how the features of claims 1 and 37 (biodisintegrable binder comprising first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form), are taught by the cited prior art. No comparison regarding the features of claims 1 and 37 vis-à-vis the cited prior art was made.

With respect to the secondary references, Applicant reiterates the arguments previously made by Applicant regarding the deficiencies of Hauschild et al., Escandon et al., and the Unger references. None of these references discloses the claimed injectable or insertable solid or semi-solid dosage form for producing specific necrosis of tissue that comes into contact with the tissue. Further, there is no suggestion in these references to modify the treatments or injections of these references to result in the pending claims, either singly or in combination nor is there any reasonable expectation of success that combining the teachings will result in the claimed dosage form.

Finally, Applicants respectfully state that the key to supporting any rejection under 35 U.S.C. §103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. §103 should be made explicit. The Court quoting *In re Kahn,* 441 F.3d 977, 988,

78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

Applicants state that the Examiner has not provided such a rational underpinning to support his conclusion of obviousness.

In light of the above remarks, Applicants state that the rejection under 103(a) has been obviated and all outstanding issues have been resolved. Thus, reconsideration and withdrawal of this rejection under 35 U.S.C. 103(a) is respectfully requested.

CONCLUSION

Applicants submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application at large, the Examiner is requested to telephone the Applicant's attorney at the number listed below in order to resolve any outstanding issues in this case.

Respectfully submitted,

Dated: September 19, 2010

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